IPHA CLINICAL TRIALS ACTIVITY COMPARISON REPORT, 2025

19th May 2025

Executive Summary

1. A review of clinical trial start dates[1] in 2023 or 2024 in Ireland, indicates a 34% increase in the number of pharmaceutical industry sponsored clinical trials commenced in that two-year period. However, while this increase is welcome, the increase in other comparator countries was greater. The time to 'first patient in' also improved in Ireland from 2023 to 2024 in that two-year period with a 31% decrease (the time from clinical trial start date to recruitment start date).

2. A total of 75 pharmaceutical industry sponsored clinical trials were commenced[1] in Ireland in 2023 and 2024.

3. Ireland conducts fewer pharmaceutical industry sponsored clinical trials in total and per capita (100,000) than many of its European counterparts. In fact, for the year 2024, Ireland was placed 18th out of 27 EU countries, per capita, for the conduct of clinical trials. Denmark had the highest number of pharmaceutical industry sponsored clinical trials per capita in Europe, followed by Belgium.

4. Denmark, which is of similar economic wealth and population to Ireland, commenced over three times (229) more pharmaceutical industry sponsored clinical trials than Ireland (75) during this period.

[1] i.e. with a clinical trial start date presented on the Clinical Trials Information System (CTIS), referring to the date when recruitment for the clinical trial is opened in Member State concerned

I. Introduction

This year's analysis using Clinical Trials Information System (CTIS) examines how the level of clinical research activity in Ireland compares with other EU counterparts. We also examine the number of pharmaceutical industry sponsored clinical trials, planned patient numbers, number of sites and time to 'first patient in'.

II. Objectives

- To assess how many clinical trials are currently recruiting in Ireland, and how many of those are pharmaceutical industry sponsored clinical trials.
- To determine the number of pharmaceutical industry sponsored clinical trials currently recruiting in Ireland in different therapeutic areas and trial phases.
- To study pharmaceutical industry sponsored clinical trials in Ireland with a clinical trial start date between 31.01.23 – 31.12.24, analyse the total number of clinical trials, total patients planned, total site locations and the time to 'first patient in'.
- To elucidate how many pharmaceutical industry sponsored clinical trials with clinical trial start dates between 2023-2024 in Ireland, were conducted in rare diseases.
- To compare the number of pharmaceutical industry sponsored clinical trials in Ireland with those in Denmark (with country specific clinical trial start dates in 2023-2024).
- Comparison of the total patient numbers planned, number of sites and time to 'first patient in' where a pharmaceutical industry sponsored clinical took place in both Ireland and Denmark.
- Evaluation of the number of pharmaceutical industry sponsored clinical trials conducted in Ireland compared to the EU27 per capita (100,000).

III. Methods

Clinical Trials Regulation 536/2014 (CTR) mandates the population of the CTIS with specific information by those conducting clinical trials. Therefore, it is considered to be the definitive source of information on this topic and was used as the source data for this year's report. The CTR applies to all interventional clinical trials in the European Economic Area involving a medicine for human use.

On 31.01.22 the CTIS public portal went live, with any new clinical trial applications from 31.01.23 onwards having to be submitted via the CTIS. Any trials that started before 31.01.23 and still ongoing after 31.01.25 must also be transferred to this system. If a clinical trial started before 31.01.23 and ended by 31.01.25, this would not have been captured on CTIS and is not analysed in this report.

(a) CTIS information was downloaded on 13.03.25 and Ireland was filtered for the following.
   - Study phase: Phase I – Phase IV
   - Sponsor type: Pharmaceutical company and Industry
   - Status: 1) Authorised recruiting, 2) ongoing recruiting, 3) ongoing recruitment ended and 4) ended

(b) For clarity while viewing the results section, additional information on dates is listed below.

- The clinical trial start date on CTIS refers to the date when recruitment for the clinical trial is opened in Member State concerned.
- The recruitment start date on CTIS is defined as the date of the first visit of the first subject.

Clinical trial start dates, recruitment start dates and information on early terminations are reported in CTIS by each sponsor. If the CTIS indicates that a pharmaceutical industry clinical trial terminated early in Ireland, it was removed from the analysis in this report *(this was a small cohort and the reasons were (1) Investigator/site related, (2) Reprioritisation of trial, (3) Safety related and (4) Sponsor decision).*

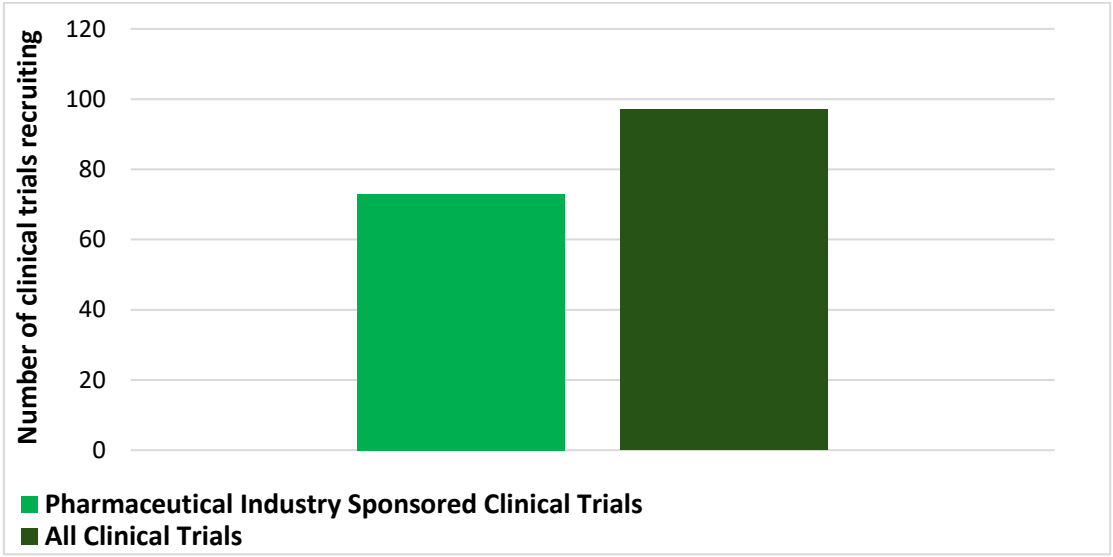
IV. Results

Clinical trials recruiting in Ireland as of March 2025

a) Comparison of 1) all clinical trials and 2) pharmaceutical industry sponsored clinical trials recruiting in Ireland as of March 2025

As of March 2025, 97 clinical trials in Ireland had a status of either authorised recruiting (the trial is authorised, recruitment opened but no one has been recruited yet) or ongoing recruiting (the trial is ongoing, recruitment opened, and the first participant has been recruited). From this cohort, 75% are sponsored by pharmaceutical companies, see Figure 1 (73/97 clinical trials).

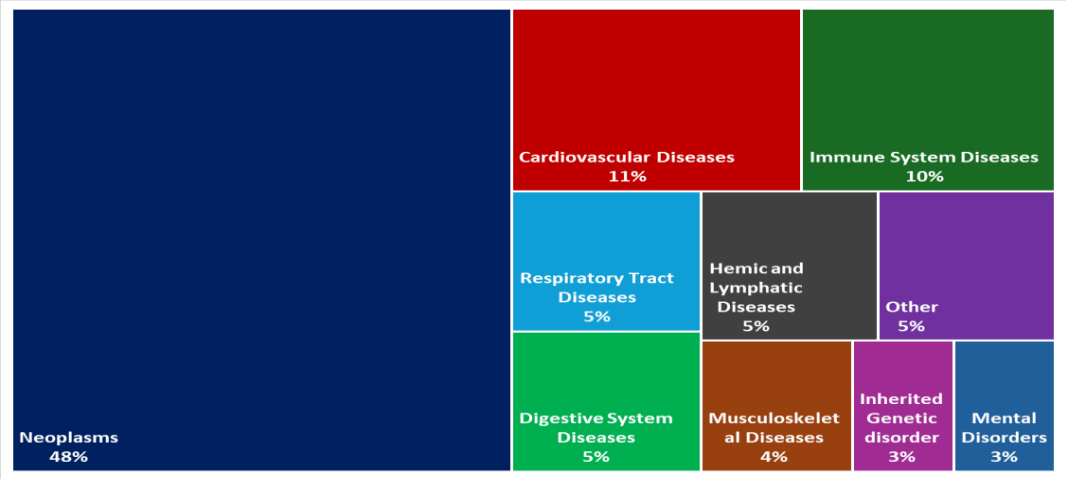
Figure 1: Currently recruiting pharmaceutical industry sponsored clinical trials and all clinical trials in Ireland



b) Breakdown of therapeutic areas for pharmaceutical industry sponsored clinical trials recruiting in Ireland as of March 2025

Oncology research is the leading therapeutic area for pharmaceutical industry sponsored clinical trials in Ireland, with nearly half (48%) of all currently recruiting (n=73) trials occurring in this therapeutic area. Clinical trials in cardiovascular disease account for 11%, with immune system diseases representing 10%. The other therapeutic areas currently recruiting in Ireland are detailed in Figure 2.

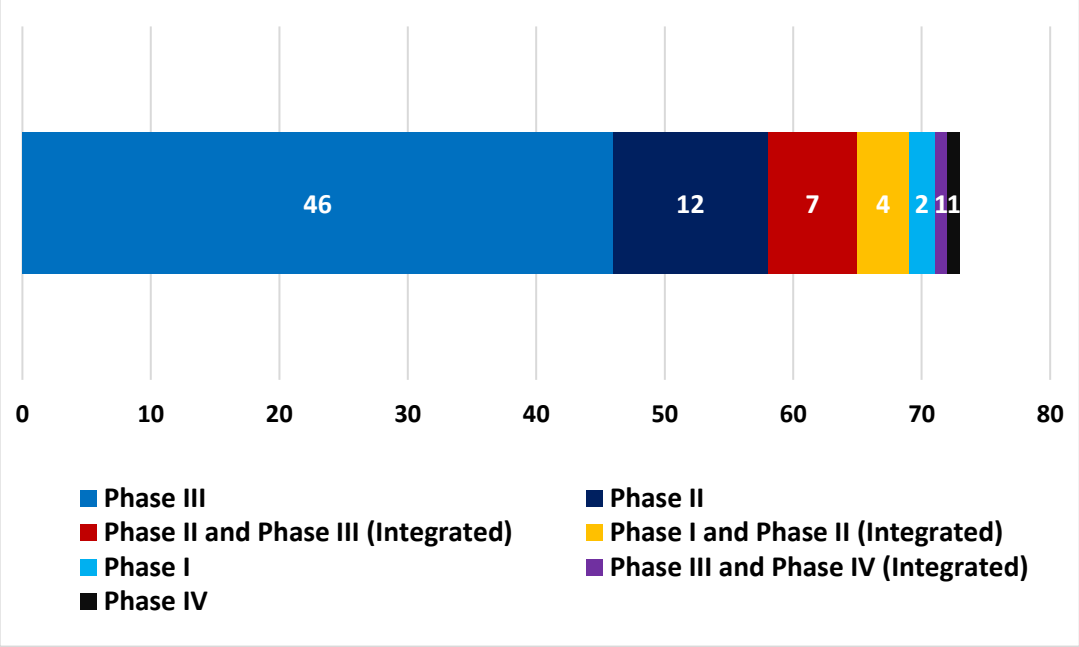
Figure 2: Pharmaceutical industry sponsored clinical trials recruiting by therapeutic area as of March 2025



c) Pharmaceutical industry sponsored clinical trials recruiting as of March 2025 split into their phases

Nearly 90% of pharmaceutical industry sponsored clinical trials recruiting (n=73) are either Phase III (63%), Phase II (16%) or Phase II & III integrated (10%), see Figure 3.

Figure 3: Pharmaceutical industry sponsored clinical trials as of March 2025 by trial phase



Conducted in Ireland with a clinical trial start date 2023-2024

d) Analysis of pharmaceutical industry sponsored clinical trials conducted in Ireland with clinical trial start date between 2023 – 2024

There were 75 pharmaceutical industry sponsored clinical trials examined with an Irish clinical trial start date between 2023 – 2024, which were either authorised recruiting (n=9), ongoing recruiting (n=42), ongoing recruitment ended (n=17) or ended (n=7). From this cohort it is estimated that a total of 773 patients will access one of the 75 pharmaceutical industry sponsored clinical trials listed on CTIS with an Irish clinical trial start date of 2023 or 2024. One third of pharmaceutical industry clinical trials listed with a clinical trial start date of either 2023 or 2024 in Ireland were deemed to be for a rare disease.

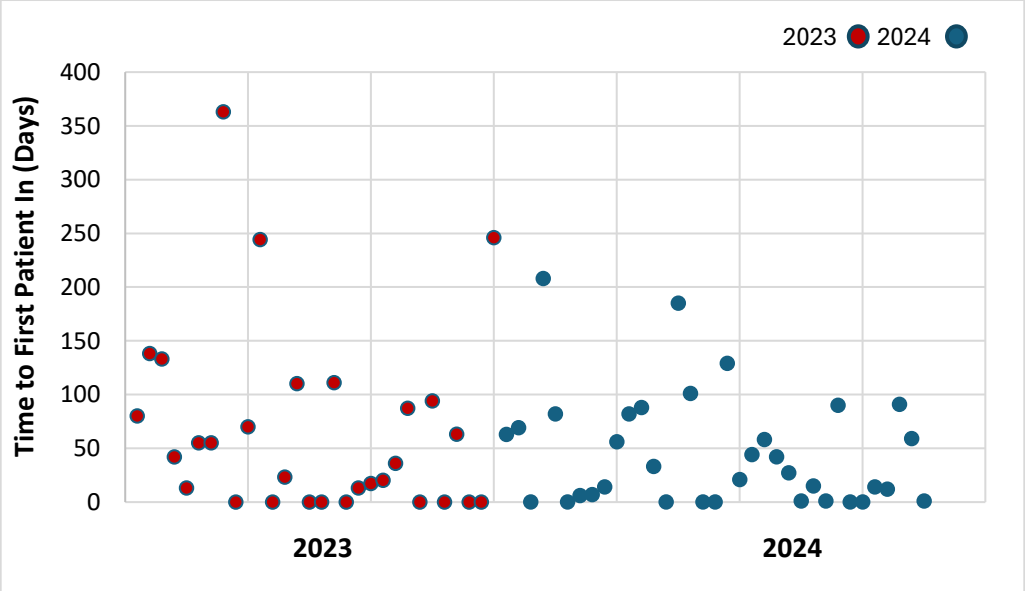
A total of 32 pharmaceutical industry sponsored clinical trials with a clinical trial start date of 2023, in Ireland, were listed on CTIS compared to 43 in 2024; an increase of 34%.

The time to 'first patient in' (from clinical trial start date to recruitment start date) was on average 56 days (n=65), with a median time of 33 days for years 2023 and 2024 combined. When comparing 2023 to 2024 for time to 'first patient in' (Table 1), it took a shorter length of time in 2024 (46 days), with a 31% decrease in time compared to 2023 (67 days).

Table 1: Time to 'first patient in', 2023 compared to 2024

Time to 'First Patient In'	2023	2024
No. of clinical trials	30	35
Average (Days)	67	46
Median (Days)	39	27

Figure 4: Time to 'First Patient In', in Ireland, 2023 compared to 2024

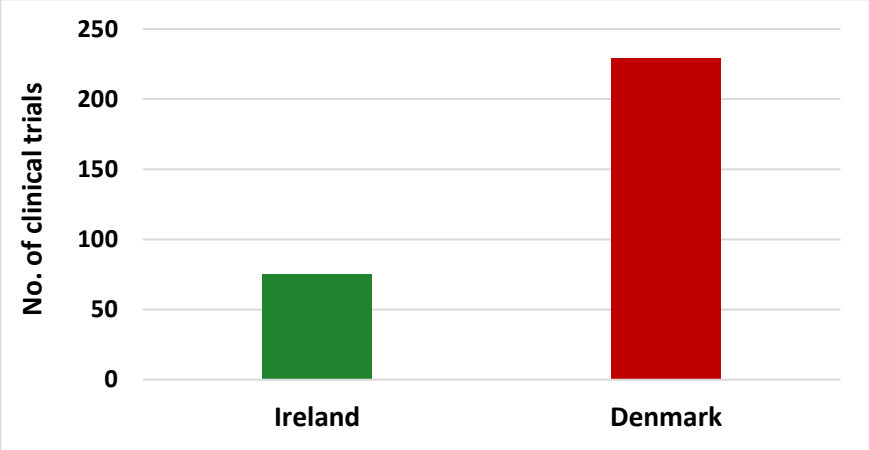


Each dot represents the time it took to get the first participant recruited for each clinical trial examined.

e) Ireland in comparison to Denmark - pharmaceutical industry sponsored clinical trial start dates from 1st Jan 2023 to 31st Dec 2024

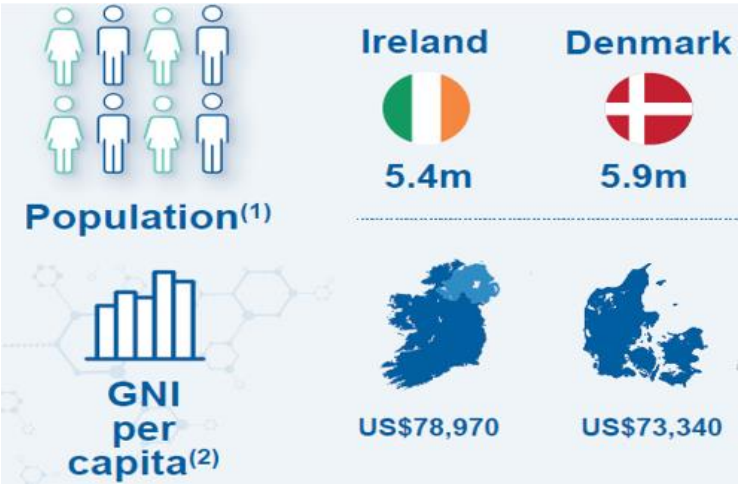
The data on clinical trials in Ireland was compared to that of Denmark over a two-year period, since it has a similar population and economic wealth to Ireland. A total of 75 pharmaceutical industry sponsored clinical trials commenced in Ireland during this period compared to 229 in Denmark – just over three times as many as Ireland.

Figure 5: Number of pharmaceutical industry sponsored clinical trials commencing between 2023-2024 in Ireland and Denmark



Ireland commenced fewer pharmaceutical industry sponsored clinical trials than Denmark between 2023 and 2024 (Figure 5), despite both countries having a similar population size and economic wealth (Figure 6).

Figure 6: Infographic on population and economic wealth in Denmark and Ireland (source: Eurostat – 2024 data [1] and the world bank – 2023 data [2])



f) Ireland vs Denmark: Pharmaceutical industry sponsored clinical trials with a clinical trial start date between 2022-2024

A total of 42 pharmaceutical industry sponsored clinical trials commenced in both Ireland and Denmark with a clinical trial start date between 2022-2024. Analysis showed that both countries had a similar number of sites involved: Ireland (98) and Denmark (105). The projected planned patient numbers participating in the clinical trials differed, with Ireland estimated at 362 patients versus 609 patients in Denmark, representing 51% more patients accessing these clinical trials in Denmark compared to Ireland for the cohort analysed.

Examining the time from clinical trial start date to recruitment start date for both countries (n=36), Ireland had an average time to 'first patient in' of 50 days compared to Denmark taking 63 days. However, the 63 days for Denmark was due to one outlier, thus when reviewing the median time, Ireland took 27 days compared to 19 days for Denmark.

g) Ireland in comparison to EU27 for the number of pharmaceutical industry sponsored clinical trials conducted per capita (100,000) that had an EU/EEA clinical trial start date in 2024

This analysis was conducted in April 2025, and it reviewed pharmaceutical industry sponsored clinical trials in all EU27 countries on CTIS with an EU/EEA clinical trial start date in 2024. The status selected for each country were authorised with recruitment pending, authorised recruiting, ongoing recruiting and ongoing recruitment ended.

Ireland is placed 18th (0.95) when examining the EU27 per capita (100,000) in terms of the number of pharmaceutical industry sponsored clinical trials with overall EU/EEA clinical trial start date of 2024. Spain had the most pharmaceutical industry sponsored clinical trials (613) in the EU27, but per capita are in 10th position. Denmark (2.50) was placed 1st per capita followed by Belgium in 2nd place (2.47). For the number of pharmaceutical industry clinical trials Germany (526) and France (467) were placed 2nd and 3rd, respectively, but per capita they were both ranked below Ireland (see Table 2).

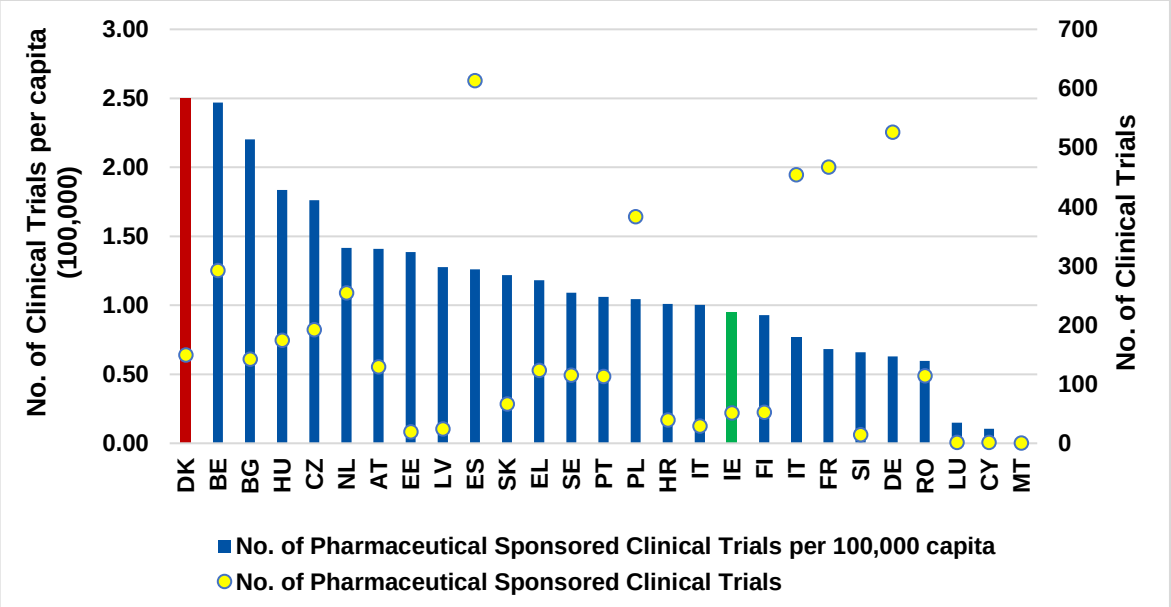
Table 2: Pharmaceutical industry sponsored clinical trials in EU27 countries per capita (100,000) in 2024

Ranking	Country	Per capita (100,000)
1	Denmark	2.50
2	Belgium	2.47
3	Bulgaria	2.20
4	Hungary	1.84
5	Czech Republic	1.76
6	Netherlands	1.42
7	Austria	1.41
8	Estonia	1.39
9	Latvia	1.28
10	Spain	1.26
11	Slovakia	1.22
12	Greece	1.18
13	Sweden	1.09
14	Portugal	1.06
15	Poland	1.05
16	Croatia	1.01
17	Lithuania	1.00
18	**Ireland**	**0.95**
19	Finland	0.93
20	Italy	0.77
21	France	0.68
22	Slovenia	0.66
23	Germany	0.63
24	Romania	0.60
25	Luxembourg	0.15
26	Cyprus	0.10
27	Malta	0.00

In 2024, the then Minister for Health, announced that he wanted to double the number of clinical trials occurring in Ireland to make Ireland more comparable with other top European performers, such as a Denmark.

If Ireland doubles the number of pharmaceutical industry sponsored clinical trials from 51 (Figure 7) to 102, it would move Ireland from 18th position (Table 2) to 4th position (1.91 per 100,000) within the EU27.

Figure 7: Pharmaceutical industry sponsored clinical trials in EU27 countries per capita (100,000) in 2024



V. Conclusion

CTIS[2] data indicated an increase of 34% in the number of pharmaceutical industry sponsored clinical trials commencing in Ireland from 2023 to 2024 and a decrease of 31% in the time to *'first patient in'* during the same period. Despite this, in 2024, Ireland was placed 18th out of 27 EU countries in terms of pharmaceutical industry sponsored clinical trials per capita (100,000). This means that Ireland lags behind most other European countries in relation to the number of pharmaceutical industry sponsored clinical trials conducted based on 2024 data.

Lack of standardisation of start-up requirements, delays in hospitals of the sign-off of key documents and the lack of a permanent clinical research nurse post for each teaching hospital can lead to many months of delays in the start-up of clinical trials. Not only does this prevent patients in Ireland receiving life changing and often lifesaving treatments but once the trial is finally approved the patients that were earmarked to join that trial are often no longer in a point in their disease that fits that trial so they miss out. Furthermore, recruitment targets for the trial are not met and the reputation of the site, as a centre to run a trial, is adversely affected.

There is clear published evidence that by including patients in clinical trials their health can improve substantially. Furthermore, more research-active hospitals can have better healthcare outcomes overall, not just for those participating in the clinical trials. Finally, each patient

[2]Data from the European Medicines Agency's Clinical Trials Information System (CTIS)

participating in a clinical trial generate a benefit to the economy and saving to the hospital where the clinical trial is being conducted.

Healthcare providers in Irish hospitals and academic institutions have shown that they have the ability to participate in, and drive, world-class research. We believe that Ireland can play a leading role in the provision of clinical trials in Europe but to do that, it is essential that we have a predictable, transparent and efficient clinical research system to compete internationally and to attract clinical trials.

IPHA has played its part – IPHA has collaborated with the State Claims Agency and HSE in the creation of the standard Clinical Trial Indemnity Form and model Clinical Trial Agreement, respectively, which have substantially improved the start-up efficiency of clinical trials. We are continuing to work hard to remove other barriers, create a better environment for the conduct of clinical trials in Ireland and ensure that Irish patients can access key life-changing trials in Ireland.

In this regard, IPHA welcomes the work of the National Clinical Trials Oversight Group, established by the Minister for Health and that that the goal to increase clinical trials is included in the Program for Government. IPHA has dedicated representation in this group and urges the work of this group to continue so that more patients in Ireland can be included in clinical trials. Including patients in clinical trials is critical in developing new innovative treatments and, ultimately, in improving the nation's health.

VI. Recommendations

IPHA continues to urge reforms in the clinical trials process to help accelerate new medicines development and raise standards of care. In particular, we support the implementation of the interim recommendations of the National Oversight Group to Support the Expansion of Clinical Trials. These are reflected in our five key asks:

1. Standardise clinical trial start-up requirements (including Data Protection Impact Assessments) and timelines for hospitals;

2. Designate specific clinical trial signatories in each hospital with a standard sign-off process;

3. Measure and track KPIs and embed research into clinical care;

4. Appoint at least one permanent clinical research nurse post for each teaching hospital;

5. Ensure the development of a robust, effective and efficient digital healthcare system to help speed up patient identification.

VII. Useful references

- National Clinical-Trials-Oversight-Group-Interim-Recommendations[3]
- Future Investment in Clinical Research report
- Independent report on Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report - 26 May 2023[4]

[3] national-clinical-trials-oversight-group-interim-recommendations.pdf

[4] https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report